VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS

PCT

INTERNATIONALER RECHERCHENBERICHT

(Artikel 18 sowie Regeln 43 und 44 PCT)

Aktenzeichen des Anmelders oder Anwalts	**WEITERES VORGEHEN**	siehe Mitteilung über die Übermittlung des internationalen Recherchenberichts (Formblatt PCT/ISA/220) sowie, soweit zutreffend, nachstehender Punkt 5
K-42922-25		
Internationales Aktenzeichen	Internationales Anmeldedatum *(Tag/Monat/Jahr)*	(Frühestes) Prioritätsdatum *(Tag/Monat/Jahr)*
PCT/EP 00/ 03350	13/04/2000	30/06/1999
Anmelder		
MEDUNA ARZNEIMITTEL GMBH		

Dieser internationale Recherchenbericht wurde von der Internationalen Recherchenbehörde erstellt und wird dem Anmelder gemäß Artikel 18 übermittelt. Eine Kopie wird dem Internationalen Büro übermittelt.

Dieser internationale Recherchenbericht umfaßt insgesamt 3 Blätter.

[X] Darüber hinaus liegt ihm jeweils eine Kopie der in diesem Bericht genannten Unterlagen zum Stand der Technik bei.

1. **Grundlage des Berichts**

   a. Hinsichtlich der **Sprache** ist die internationale Recherche auf der Grundlage der internationalen Anmeldung in der Sprache durchgeführt worden, in der sie eingereicht wurde, sofern unter diesem Punkt nichts anderes angegeben ist.

   [ ] Die internationale Recherche ist auf der Grundlage einer bei der Behörde eingereichten Übersetzung der internationalen Anmeldung (Regel 23.1 b)) durchgeführt worden.

   b. Hinsichtlich der in der internationalen Anmeldung offenbarten **Nucleotid- und/oder Aminosäuresequenz** ist die internationale Recherche auf der Grundlage des Sequenzprotokolls durchgeführt worden, das

   [ ] in der internationalen Anmeldung in Schriftlicher Form enthalten ist.

   [ ] zusammen mit der internationalen Anmeldung in computerlesbarer Form eingereicht worden ist.

   [ ] bei der Behörde nachträglich in schriftlicher Form eingereicht worden ist.

   [ ] bei der Behörde nachträglich in computerlesbarer Form eingereicht worden ist.

   [ ] Die Erklärung, daß das nachträglich eingereichte schriftliche Sequenzprotokoll nicht über den Offenbarungsgehalt der internationalen Anmeldung im Anmeldezeitpunkt hinausgeht, wurde vorgelegt.

   [ ] Die Erklärung, daß die in computerlesbarer Form erfaßten Informationen dem schriftlichen Sequenzprotokoll entsprechen, wurde vorgelegt.

2. [ ] **Bestimmte Ansprüche haben sich als nicht recherchierbar erwiesen** (siehe Feld I).

3. [ ] **Mangelnde Einheitlichkeit der Erfindung** (siehe Feld II).

4. Hinsichtlich der **Bezeichnung der Erfindung**

   [X] wird der vom Anmelder eingereichte Wortlaut genehmigt.

   [ ] wurde der Wortlaut von der Behörde wie folgt festgesetzt:

5. Hinsichtlich der **Zusammenfassung**

   [X] wird der vom Anmelder eingereichte Wortlaut genehmigt.

   [ ] wurde der Wortlaut nach Regel 38.2b) in der in Feld III angegebenen Fassung von der Behörde festgesetzt. Der Anmelder kann der Behörde innerhalb eines Monats nach dem Datum der Absendung dieses internationalen Recherchenberichts eine Stellungnahme vorlegen.

6. Folgende Abbildung der **Zeichnungen** ist mit der Zusammenfassung zu veröffentlichen: Abb. Nr. ---

   [ ] wie vom Anmelder vorgeschlagen

   [ ] weil der Anmelder selbst keine Abbildung vorgeschlagen hat.

   [ ] weil diese Abbildung die Erfindung besser kennzeichnet.

   [ ] keine der Abb.

INTERNATION R RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/EP 00/03350

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
IPK 7 A23L1/30 A61K9/48 A61K31/202 A61K31/232 A61P1/00

Nach der Internationalen Patentklassifikation (IPK) oder nach der nationalen Klassifikation und der IPK

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
IPK 7 A23L A61K A61P

Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)
EPO-Internal, WPI Data, PAJ, FSTA, BIOSIS, CHEM ABS Data

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie°	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	WO 93 13761 A (ALFATEC PHARMA GMBH) 22. Juli 1993 (1993-07-22) Seite 8, Zeile 1 - Zeile 19 Seite 11, Zeile 22 - Zeile 33 Ansprüche 1,5,12,14	1,6
Y		2-5

Y	DATABASE WPI Section Ch, Week 199711 Derwent Publications Ltd., London, GB; Class B04, AN 1997-112791 XP002143507 -& JP 09 000201 A (AMINO APPU KAGAKU KK), 7. Januar 1997 (1997-01-07) Zusammenfassung	2,3,5

	-/--	

[X] Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen

[X] Siehe Anhang Patentfamilie

° Besondere Kategorien von angegebenen Veröffentlichungen :
"A" Veröffentlichung, die den allgemeinen Stand der Technik definiert, aber nicht als besonders bedeutsam anzusehen ist
"E" älteres Dokument, das jedoch erst am oder nach dem internationalen Anmeldedatum veröffentlicht worden ist
"L" Veröffentlichung, die geeignet ist, einen Prioritätsanspruch zweifelhaft erscheinen zu lassen, oder durch die das Veröffentlichungsdatum einer anderen im Recherchenbericht genannten Veröffentlichung belegt werden soll oder die aus einem anderen besonderen Grund angegeben ist (wie ausgeführt)
"O" Veröffentlichung, die sich auf eine mündliche Offenbarung, eine Benutzung, eine Ausstellung oder andere Maßnahmen bezieht
"P" Veröffentlichung, die vor dem internationalen Anmeldedatum, aber nach dem beanspruchten Prioritätsdatum veröffentlicht worden ist
"T" Spätere Veröffentlichung, die nach dem internationalen Anmeldedatum oder dem Prioritätsdatum veröffentlicht worden ist und mit der Anmeldung nicht kollidiert, sondern nur zum Verständnis des der Erfindung zugrundeliegenden Prinzips oder der ihr zugrundeliegenden Theorie angegeben ist
"X" Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann allein aufgrund dieser Veröffentlichung nicht als neu oder auf erfinderischer Tätigkeit beruhend betrachtet werden
"Y" Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann nicht als auf erfinderischer Tätigkeit beruhend betrachtet werden, wenn die Veröffentlichung mit einer oder mehreren anderen Veröffentlichungen dieser Kategorie in Verbindung gebracht wird und diese Verbindung für einen Fachmann naheliegend ist
"&" Veröffentlichung, die Mitglied derselben Patentfamilie ist

Datum des Abschlusses der internationalen Recherche	Absendedatum des internationalen Recherchenberichts
26. Juli 2000	08/08/2000

Name und Postanschrift der Internationalen Recherchenbehörde	Bevollmächtigter Bediensteter
Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Dekeirel, M

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Formblatt PCT/ISA/210 (Blatt 2) (Juli 1992)

Internationales Aktenzeichen
PCT/EP 00/03350

C.(Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie°	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/EP 00/03350

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PATENT SPECIFICATION

436,236

Application Date : April 26, 1934. No. 12590/34.

Complete Specification Accepted : Oct. 8, 1935.

COMPLETE SPECIFICATION

Improvements in and relating to a Therapeutic Capsule

I, KARL WILHELM SCHMIDT, of German nationality of Innere Cramer-Klettstrasse 6, Nürnberg, Germany, do hereby declare the nature of this invention and in what manner the same is to be performed, to be particularly described and ascertained in and by the following statement:—

This invention relates to a therapeutic capsule for introducing medicaments into cavities in the body, in which there is no digestive action.

Known capsules of this kind which are made of gelatine have the drawback that they do not dissolve sufficiently quickly and completely. Such capsules are therefore not suitable for purposes for which it is desired to obtain the action of the medicament immediately after the introduction of the capsule into the cavity and they do not permit of subsequent removal of the remains of the capsule from the cavity.

According to the invention the capsule consists of a mixture of binding agents with readily soluble salts or with sugar preparations or with urea. The capsule is entirely or partially filled with a medicament, preferably in powder form, and is introduced into the cavity. In the cavity it dissolves or opens after a few minutes and liberates the medicament, so that the latter comes in contact with the tissues of the cavity for exerting its curative effect.

According to a modified form of the invention the capsule consists of a water pervious substance and the medicament has effervescent powder mixed therewith. When the capsule comes into contact with water the moisture absorbed by the water pervious substance will be transmitted to the medicament and then the effervescent powder will cause expansion to take place and will open or destroy the capsule.

It has already been proposed to use an envelope of unleavened bread in which a suppository or the like is contained. The provision of effervescent material according to the invention has the advantage of causing the device to open much more rapidly.

Finally the capsule as above defined, filled with a medicament or a disinfectant or a cosmetic, may be used in bath water, in washing water or waters used for skin treatment. It dissolves in the water, whereby the medicament or the like contained in the capsule is conveyed into the water.

In carrying the invention into effect the procedure may be as follows:

(1) The capsule consists of a substance which is soluble in secretions of the body and consists of a mixture of binding agents with readily soluble salts or with sugar preparations or with urea. In the capsule is a medicament. The capsule is introduced into the cavity, where it dissolves, the medicament being liberated and acting on the tissues of the cavity.

(2) The soluble capsule is filled with a medicament and is closed with a stopper or a cover. The stopper or cover consists of a substance which melts readily in the heat and moisture of the body. An effervescent powder is mixed with the medicament. The closed capsule is introduced into the cavity. There the stopper or cover first melts and thus opens the capsule. The moisture of the body enters into the capsule and re-acts with the medicament contained in the capsule and moistens the effervescent powder in the medicament, which will cause expansion to take place. This hastens the dissolving of the capsule or destroys it.

(3) The capsule filled with a medicament consists of a water-pervious substance and is provided with a cover. The medicament is mixed with effervescent powder. The capsule is first dipped in water and is then introduced into the cavity. The moisture absorbed by the capsule is transmitted to the medicament contained therein. This causes the effervescent powder contained in the medicament to become moist. The effervescent powder causes expansion to take place and opens the capsule cover or destroys the capsule.

(4) The capsule consisting of a water-soluble substance and filled with a medicament or a disinfectant or a cosmetic is thrown in water which is in a bath, a hand basin or some other vessel. In the water the capsule becomes completely dissolved. By this means the medicament or the like passes into the water and imparts to it the desired

[*Price* 1/-]

Price 4s 6d

Price 2s.

quality. In this way for instance bath salts, water-soluble medicaments, disinfectants and cosmetics or other ingredients may be added to bath or washing water or to waters for skin treatment.

(5) In the modification according to (4), the substance of which the capsule is made or the medicament or the like contained in it is mixed with an effervescent powder. When the capsule is thrown into the water, the effervescent powder becomes moist, causes expansion to take place and hastens the dissolving of the capsule and destroys it.

The capsule which is soluble in aqueous secretions of the body consists of a mixture of readily soluble salts with binding agents or of a mixture of sugar preparations or urea with binding agents. The readily soluble salt may be common salt. The employment of urea is of special advantage, as the capsule material with its urea constituent dissolves very easily and quickly, without being felt and without leaving any residue. Suitable binding agents are: tragacanth, starch flour or soap. The water-soluble capsule consists of a mixture of easily soluble salts or sugar preparations or urea with binding agents. As the easily soluble salt, common salt may be used. The binding agents are tragacanth, starch flour or soap.

The water-pervious capsule consists for instance of so-called wafer dough which is made of potato flour and water.

The easily melting stopper of the capsule consists of cocoa-butter.

The effervescent powder consists of a mixture of bicarbonate of soda and tartaric acid.

As medicaments are preferably used germicidal powders.

When the effervescent powder forms a constituent part of the capsule substance, the water-soluble capsule may consist of a mixture of readily soluble salts or sugar preparations, effervescent powder and binding agents.

In the accompanying drawing two constructional examples of the invention are illustrated. Fig. 1 shows one constructional form in cross-section. The other constructional form is shown in Figs. 2 and 4 in cross-section and in Fig. 3 in plan view.

In the constructional form shown in Fig. 1 the capsule *a* is closed by means of a stopper *b* and contains the medicament filling *d*. The capsule *a* consists of a mixture of common salt or urea with binding agents. The stopper *b* consists of cocoa-butter. The medicament is a germicidal powder. The effervescent powder may form a constituent either of the capsule *a* or be mixed with the medicament *d*, or no effervescent powder at all need be used.

In the constructional form shown in Figs. 2 to 4 the capsule *a* and its cover *b'* consist of a water-pervious substance, namely a dough of potato flour and water. The cover *b'* has a central opening *c*. In the capsule is the medicament *d* which consists of a mixture of germicidal powder and effervescent powder. In addition the capsule contains an insertion *e* which is disposed between the powder *d* and the cover *b'* and is in the form of a thin disc which, resting on the powder *d* lies at a distance below the cover *b'*, so that between the cover and the disc there is a layer of air *f*. The insertion *e* is of such a nature that it rapidly absorbs and transmits water. For this purpose there may be used a thin disc made of potato flour and water, a suitably prepared paper disc, a cellulose disc or a small wad of cotton wool.

When it is to be used, the capsule arranged and covered as shown in Fig. 2 is moistened with water, being for instance dipped into water, and is thereupon introduced into the cavity in the body. Through being moistened the capsule *a* with the cover *b'* is in the first instance softened to such an extent that the two parts still retain their shape, so that they can be inserted without difficulty. The water entering the capsule through the opening *c* in the cover is absorbed by the insertion *e* and transmitted to the powder *d*. The latter is caused to effervesce, lifts the cover *b'* (Fig. 4) and passes into the cavity. The capsule *a* and the cover *b'* dissolve gradually in the cavity. The insertion *e* is (according to its nature) also dissolved or subsequently removed by irrigation.

The insertion *e* may be omitted. In that case the powder *d* is moistened through the wall of the capsule *a*.

Having now particularly described and ascertained the nature of my said invention and in what manner the same is to be performed, I declare that what I claim is:—

1. A therapeutic capsule for introducing medicaments into cavities in the body, in which there is no digestive action, characterised by the feature that the capsule consists of a mixture of binding agents with readily soluble salts or with sugar preparations, or with urea.

2. A therapeutic capsule as claimed in claim 1, characterised by the feature that the capsule is provided with a stopper consisting of a substance which melts readily in the heat and moisture of the body.

3. A therapeutic capsule as claimed in claims 1 and 2, characterised by the feature that the substance of which the capsule consists or the medicament enclosed in the capsule is mixed with a powder which, on becoming moist, causes expansion to take place, thereby opening or destroying the capsule.

4. A therapeutic capsule as claimed in claims 1 to 3, characterised by the feature that an insertion of water-pervious material is disposed in the capsule in contact with the powder and that in the capsule cover are one or more openings which, when the cover is in the closed position, lie above the insertion, a layer of air being preferably interposed between the cover and the insertion.

5. A therapeutic capsule as claimed in Claims 1 to 4, characterised by the feature that the capsule serves as a container for medicament, disinfectants or cosmetics intended to be conveyed into bath water, washing water or waters for treating the skin.

6. A therapeutic capsule for introducing medicaments into cavities in the body, characterised by the feature that the capsule consists of a water-pervious substance and the medicament has effervescent powder mixed therewith.

7. The improved therapeutic capsule for introducing medicaments into cavities in the body, substantially as described and more particularly with reference to the accompanying drawing.

Dated this 24th day of April, 1934.

MARKS & CLERK.

Leamington Spa: Printed for His Majesty's Stationery Office, by the Courier Press.—1935.

Fig.1

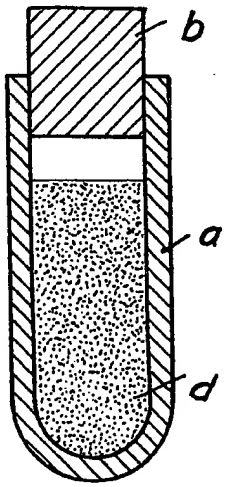


Fig.2

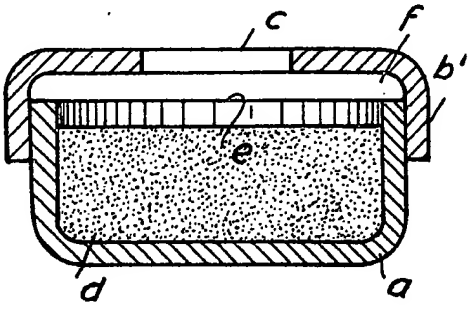


Fig.3

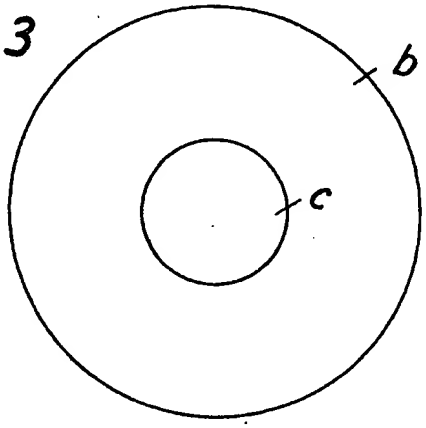
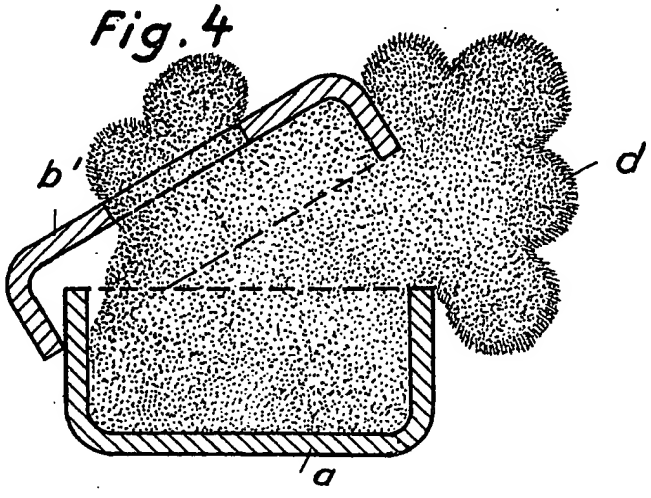


Fig.4



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ing it into the desired substance. Barium sulfide is handled in the form of an aqueous solution and only rarely is separated as a solid.

Barium sulfite, $BaSO_3$, occurs as colorless cubic (or hexagonal) crystals, with solubility 0.02 g/100 g H_2O at 0°C.

Barium titanate, $BaTiO_3$ (mp, ca 1625°C), has both ferroelectric and piezoelectric properties and is used in sonar equipment, in phonograph cartridges, capacitators, and other electronic equipment.

TRUMAN KIRKPATRICK
The Sherwin-Williams Company

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D.A. Brobst, "Barite" in D.A. Brobst and W.P. Pratt, eds., *United States Mineral Resources, U.S. Geological Survey Professional Paper 820*, U.S. Government Printing Office, Washington, D.C., 1973, pp. 75–84.

BARRIER POLYMERS

The general theory of permeation of a gas or liquid through a polymer matrix states that the permeation rate is the product of a diffusion term and a solubility constant of the gas–liquid in the polymer matrix, each of which is often independent of the other. The process of permeation through a polymeric barrier involves four steps: absorption of the permeating species into the polymer wall; solubility in the polymer matrix; diffusion through the wall along a concentration gradient; and desorption from the outer wall. In order to be a good barrier polymer, the material must have some degree of polarity such as contributed by the nitrile, ester, chlorine, fluorine, or acrylic functional groups; high chain stiffness; inertness; close chain-to-chain packing by symmetry, order crystallinity, or orientation; some bonding or attraction between chains; high glass-transition temperature T_g. Permeability also is affected by fillers and additives, moisture content, temperature, thickness, and molecular structure of permeating gas or liquid.

Measurement of Barrier Properties

The most common method of measuring gas permeation uses a Dow Permeation Cell. Water permeation through a polymer generally is measured by gravimetric weight loss of a sealed water-filled container made from the test polymer or by gravimetric weight loss of a special metal cup (such as the Paine cup) which uses the test polymer as a lid. Organic-liquid permeation usually is measured by using a filled molded container made of the test polymer and noting gravimetric weight loss. In all measurements of gas or liquid permeation, it is necessary to allow time for equilibrium rates to become established or erroneous values will be obtained.

A high barrier polymer can be defined as one that exhibits a high resistance to molecular flow of a permeating agent or agents through the polymer matrix. To qualify as a truly high barrier polymer, the following limits of permeation should apply based on studies of the packaging of products that are sensitive to gases, liquids, or organic-vapor diffusion: a gas transmission of not more than 10 cm^3 of oxygen per 0.025 nm of polymer per 645 cm^2 (10 $in.^2$) of surface per day per 101 kPa (760 mm Hg) driving force at 23°C and humidity conditions of use; water permeation of not more than 7 g per 0.025 mm per 645 cm^2 per day in direct contact with water at 38°C and with low rh air circulating on the downstream side of the barrier; and less than 5% loss of an organic substance by absorption and/or diffusion from a solution of the substance in contact with the polymer for a period of at least 6 months at 23°C (or equivalent).

Table 1 lists currently available polymers meeting the requirements of high barrier polymers and compares their permeation rates for oxygen, carbon dioxide, water, and organic compounds. There are also several well-known polymers that come close to meeting the limits set for gas and water permeation and that can be considered as moderate barrier polymers: nylon-6; nylon-6,6; Delrin, Penton, poly(vinyl fluoride), poly(methyl methacrylate); nylon-11; and XT Polymer. Some polymers show excellent gas barrier properties but poor water barrier rates, eg, poly(vinyl alcohol) (dry) and cellophane (dry-uncoated); and others are poor gas barriers but good water barriers, eg, high density polyethylene, polypropylene, Teflon (polytetrafluoroethylene), polybutene, low density polyethylene, Surlyn ionomer, and butyl rubber.

Absorption from Dilute Solutions

A property related to barrier properties, but more subtle, is that of the absorption by the polymer of the molecules of a solution in contact with it. In many cases, these can be large bulky organic molecules, and the actual diffusion through the polymer matrix can be slow. But, because of the depletion of some molecules from the packaged solution, the properties of the product are altered as in the case of direct permeation of the product through the polymer. This is especially true if the absorbed molecules are related to taste, odor, or flavor of the contacting food or beverage. This phenomenon is directly proportional to the barrier properties of the polymer in most cases.

The main use of high barrier polymers is packaging, especially for foods and beverages, as a replacement for glass and metal containers. Light weight, nonshatterability, ease of disposal by incineration, and potentially lower costs are the forces behind the increasing popularity of barrier plastics. To be a successful food-and-beverage packaging material, the polymer must resist absorption from dilute solutions, retain carbon dioxide, protect food from oxygen, be durable, and have good creep strength, clarity, packaging processability, antistatic properties, and general chemical resistance (see Table 2).

The high nitrile polymers are the most interesting of the barrier polymers to be introduced. The permeation of any high nitrile polymer depends upon the level of nitrile, the type of nitrile, and the amount and type of comonomer and the presence of additives. Although the amount of nitrile is controlling, the comonomer can have significant barrier effects. For instance, whereas a 70:30 acrylonitrile–styrene copolymer

Table 1. Permeability Properties of High Barrier Polymers

Polymer	Polymer class	Permeation rates: Oxygen[a]	Carbon dioxide[a]	Water[b]
poly(vinylidene chloride)	halogenated	0.4	1.2	7.9
Lopac[c]	nitrile	3.9	12	200
Barex	nitrile	4.3	12	240
Cycopac[d]	nitrile	4.3	16	200
Saran wrap	halogenated	5.1	18	20
epoxy (bisphenol A; amine cure)	thermoset	12	35	160
Kel-F (polychlorotrifluoro-ethylene)	halogenated	13	47	12
Trogamid T	polyamide	18	47	205
Kynar [poly(vinylidene fluoride)]	halogenated	18	59	39
poly(ethylene terephthalate)	polyester	20–39[e]	47–79[e]	80–160[e]
nylon-6,9; nylon-6,10	polyamide	22	47	240
phenoxy [poly(phenylene oxide)]	aromatics	28	59	180
poly(vinyl chloride)	halogenated	31–59[f]	79–157[f]	80–120[f]

[a] At 23°C (100% rh), $(m^3 \cdot m)/(m^2 \cdot d \cdot PPa)$. To convert PPa to bar, multiply by 10^{10}.

[b] $kg \cdot cm/(im^2 \cdot d)$ at 38°C (100% rh).

[c] Acrylonitrile (70%)–styrene copolymer used for manufacturing Monsanto Cycle-Safe container.

[d] A similar polymer, Vicobar (DuPont), is no longer made. Vicobar had similar barrier properties.

[e] Depends on exact level of crystallinity and orientation.

[f] Depends on exact compound formulation.

Table 2. Properties of True High-Barrier Polymers

Polymer	Tensile strength, MPa[a]	Drop impact (toughness)	Creep (cold flow)	Heat-distortion temperature, °C	Optical properties	Processability
Lopac, oriented	103	good	low	>90	clear	fair
Lopac, unoriented	76	poor	low	>90	clear	fair
Cycopac	69	good	low	90	clear	fair
Barex 210	55	good	moderate	71	clear	fair
Kel-F	41	good	moderate	>150	clear	poor
Trogamid T	62	fair-good	high	>90	clear	fair
Kynar [poly(vinylidene fluoride)]	41	fair	low	>90	opaque	poor
poly(ethylene terephthalate), unoriented	48	poor	low	>90	clear/opaque	poor
poly(ethylene terephthalate), oriented	>70	good	low	>90	clear	fair
nylon-6,10	55	good	moderate	>90	translucent	fair
phenoxy resin	62	fair	low	>120	clear	fair-poor
poly(vinyl chloride) (rigid)	52	fair-good	high	66	clear	fair

[a] To convert MPa to psi, multiply by 145.

has an oxygen permeation rate of 4.0, the corresponding acrylonitrile–methyl acrylate copolymer has an oxygen permeation of 3.2. This improvement in gas barrier is related to the polarity of the acrylate.

Poly(ethylene terephthalate) (PET), commonly called polyester, has a balance of properties and economics that make it useful for 1-L (34-oz) and 2-L (68-oz) soft-drink containers. Characteristics of the polyester bottle that have led to its commercialization fall into three categories: physical properties (clear, glossy, light, strong, and shatterproof); chemical properties (resistant to mineral and organic acids and weak alkalies at room temperature and to bleaches, oxidizing agents, and most common solvents and oils: protects taste of the beverage); and properties relevant to government regulations of PET as a food additive (*Title 21*, CFR, *121 (F)*).

Restrictive packaging and antilitter legislation is at various stages of preparation or consideration in over 30 different state legislatures. Their passage could conceivably force a policy of returnable and refillable bottles. Currently produced PET bottles cannot be refilled.

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M. Salame, *Polym. Sci. Technol.* **6**, 275 (1974).
M. Salame and E.J. Temple, *Adv. Chem. Ser.* (135), 61 (1974).
M. Salame, *Package Eng.* **17**(8), 61 (1972).

BATTERIES AND ELECTRIC CELLS, PRIMARY

INTRODUCTION

Devices that convert chemical energy into electrical energy are commonly referred to as batteries. In these devices, electrical energy is the result of chemical reactions that give products with lower energy content. When the higher energy compounds are formed by putting electrical energy into the battery and electrical energy is later withdrawn with formation of lower energy compounds, the battery acts as an electrical energy storage device, a secondary battery. Primary batteries are devices initially assembled with high energy chemical compounds, and stored chemical energy is withdrawn as electrical energy at some later time. Batteries sold in their charged state and discarded without recharge are called primary batteries. Fuel cells are a special class of primary batteries in which the high energy reactants are fed continuously into the battery and the low energy reaction products are removed continuously.

Today, a battery may be one or many individual cells. A single electrochemical cell is composed of a negative electrode and a positive electrode separated by an electrolytic solution. When the cell is discharging, converting chemical energy to electrical energy, an oxidation reaction occurs at the negative electrode or anode: $Zn \rightarrow Zn^{2+} + 2\ e$. At the positive electrode or cathode during discharging, a reduction reaction occurs: $Cl_2 + 2\ e \rightarrow 2\ Cl^-$.

In electrode reactions of any compatible pair of anode and cathode processes, often called an electrochemical couple, electrons pass through the external circuit from the anode to the cathode. The circuit is completed by ionic species transferring across the cell through the intervening electrolyte. The change from electronic conduction to ionic conduction occurs at the electrodes and involves an electrochemical reaction or Faradaic reaction. Electrons cannot pass from the positive to the negative electrode through the electrolyte. If that occurs, an electronic short exists, and the cell will self-discharge. This can cause cell overheating, pressure buildup, and rupture. This factor must be considered in battery cell design.

Stoichiometric reactions shown above consist of a sequence of more elementary steps that may occur at slightly different locations on a microscopic scale. However, the reactants must approach within molecular distances of one another and products must be removed on a continuing basis for a cell to operate properly. These steps imply that electrons from the external circuit must reach or leave the reaction sites. Reaction sites must, therefore, be electronically connected to the external circuit. Usually, ionic species in the electrolyte solution must move to or away from the reaction site. The solution-phase transport causes concentration variations near reaction sites affecting the rate of reaction. There may also be ion transport through solid phases. The energy losses associated with concentration variations result in lowered cell potential called concentration overpotential. Associated with concentration overpotential is the heat produced by the energy necessary to drive ions through the solution to carry the electrical current. This energy is often called the resistance loss or ohmic loss which appears as a reduction in the cell potential, called ohmic overpotential. In addition, energy is necessary to drive the reactions taking place. This driving energy comes from conversion of chemical energy which then degrades to heat rather than producing electrical energy. Losses associated with driving the transfer of charge at electrode reaction sites result in a reduction in the cell potential called surface overpotential. The irreversible heat generated by each loss process is the appropriate overpotential times the electrical current. Understanding these loss processes and minimizing them is an important factor in battery design. There is also a reversible heat associated with cell operation. The irreversible heats are always positive, adding heat to the cell. The reversible heat can be positive or negative. Besides voltage losses, losses in overall useful energy occur because of many types of unwanted side reactions, often called corrosion reactions.

The driving force pushing electrons through an external circuit is the change in the free energy: $G = H - TS$, where H is the enthalpy or heat content, S is the entropy, and T is the absolute temperature. If there are no corrosion reactions or other unwanted or unknown side reactions, the open circuit cell potential U is related to the free energy change as follows: $\Delta G = -nFU$, where ΔG is the free energy change for the overall cell reaction based on the reversible transfer of n equivalents of electrons through the external circuit and F is the Faraday constant (96,487 C/equiv).

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J. Newman, *Electrochemical Systems*, Prentice-Hall, Inc., Englewood Cliffs, N.J., 1973.
P. Delahay, *Double Layer and Electrode Kinetics*, John Wiley & Sons, Inc., New York, 1965.
N.C. Cahoon and G.W. Heise, eds., *The Primary Battery*, Vols. 1 and 2, John Wiley & Sons, Inc., New York, 1976.

PRIMARY CELLS

The Leclanché cell, which uses an amalgamated zinc anode, an electrolyte of ammonium and zinc chlorides dissolved in water, and a manganese

9719258

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE
in its capacity as elected Office

Date of mailing: 11 January 2001 (11.01.01)	
International application No.: PCT/EP00/03350	Applicant's or agent's file reference: K-42922-25
International filing date: 13 April 2000 (13.04.00)	Priority date: 30 June 1999 (30.06.99)
Applicant: FRAUENDORFER, Friedel	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International preliminary Examining Authority on:

25 August 2000 (25.08.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer:

J. Zahra

Telephone No.: (41-22) 338.83.38

3750556

VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS

PCT

09/719258

INTERNATIONALER VORLÄUFIGER PRÜFUNGSBERICHT

(Artikel 36 und Regel 70 PCT)

Aktenzeichen des Anmelders oder Anwalts	**WEITERES VORGEHEN**	siehe Mitteilung über die Übersendung des internationalen vorläufigen Prüfungsberichts (Formblatt PCT/IPEA/416)
K-42922-25		
Internationales Aktenzeichen	Internationales Anmeldedatum *(Tag/Monat/Jahr)*	Prioritätsdatum *(Tag/Monat/Tag)*
PCT/EP00/03350	13/04/2000	30/06/1999
Internationale Patentklassifikation (IPK) oder nationale Klassifikation und IPK A23L1/30		
Anmelder MEDUNA ARZNEIMITTEL GMBH et al		

1. Dieser internationale vorläufige Prüfungsbericht wurde von der mit der internationalen vorläufigen Prüfung beauftragten Behörde erstellt und wird dem Anmelder gemäß Artikel 36 übermittelt.

2. Dieser BERICHT umfaßt insgesamt 6 Blätter einschließlich dieses Deckblatts.

   ☒ Außerdem liegen dem Bericht ANLAGEN bei; dabei handelt es sich um Blätter mit Beschreibungen, Ansprüchen und/oder Zeichnungen, die geändert wurden und diesem Bericht zugrunde liegen, und/oder Blätter mit vor dieser Behörde vorgenommenen Berichtigungen (siehe Regel 70.16 und Abschnitt 607 der Verwaltungsrichtlinien zum PCT).

   Diese Anlagen umfassen insgesamt 2 Blätter.

3. Dieser Bericht enthält Angaben zu folgenden Punkten:

   - I ☒ Grundlage des Berichts
   - II ☐ Priorität
   - III ☐ Keine Erstellung eines Gutachtens über Neuheit, erfinderische Tätigkeit und gewerbliche Anwendbarkeit
   - IV ☐ Mangelnde Einheitlichkeit der Erfindung
   - V ☒ Begründete Feststellung nach Artikel 35(2) hinsichtlich der Neuheit, der erfinderischen Tätigkeit und der gewerblichen Anwendbarkeit; Unterlagen und Erklärungen zur Stützung dieser Feststellung
   - VI ☐ Bestimmte angeführte Unterlagen
   - VII ☒ Bestimmte Mängel der internationalen Anmeldung
   - VIII ☐ Bestimmte Bemerkungen zur internationalen Anmeldung

Datum der Einreichung des Antrags	Datum der Fertigstellung dieses Berichts
25/08/2000	20.08.2001
Name und Postanschrift der mit der internationalen vorläufigen Prüfung beauftragten Behörde: Europäisches Patentamt D-80298 München Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Bevollmächtigter Bediensteter Georgopoulos, N Tel. Nr. +49 89 2399 2634

INTERNATIONALER VORLÄUFIGER PRÜFUNGSBERICHT

Internationales Aktenzeichen PCT/EP00/03350

I. Grundlage des Berichts

1. Hinsichtlich der **Bestandteile** der internationalen Anmeldung (*Ersatzblätter, die dem Anmeldeamt auf eine Aufforderung nach Artikel 14 hin vorgelegt wurden, gelten im Rahmen dieses Berichts als "ursprünglich eingereicht" und sind ihm nicht beigefügt, weil sie keine Änderungen enthalten (Regeln 70.16 und 70.17)*):
Beschreibung, Seiten:

1-5 ursprüngliche Fassung

Patentansprüche, Nr.:

1-11 eingegangen am 22/06/2001 mit Schreiben vom 21/06/2001

2. Hinsichtlich der **Sprache**: Alle vorstehend genannten Bestandteile standen der Behörde in der Sprache, in der die internationale Anmeldung eingereicht worden ist, zur Verfügung oder wurden in dieser eingereicht, sofern unter diesem Punkt nichts anderes angegeben ist.

Die Bestandteile standen der Behörde in der Sprache: zur Verfügung bzw. wurden in dieser Sprache eingereicht; dabei handelt es sich um

- ☐ die Sprache der Übersetzung, die für die Zwecke der internationalen Recherche eingereicht worden ist (nach Regel 23.1(b)).
- ☐ die Veröffentlichungssprache der internationalen Anmeldung (nach Regel 48.3(b)).
- ☐ die Sprache der Übersetzung, die für die Zwecke der internationalen vorläufigen Prüfung eingereicht worden ist (nach Regel 55.2 und/oder 55.3).

3. Hinsichtlich der in der internationalen Anmeldung offenbarten **Nucleotid- und/oder Aminosäuresequ nz** ist die internationale vorläufige Prüfung auf der Grundlage des Sequenzprotokolls durchgeführt worden, das:

- ☐ in der internationalen Anmeldung in schriftlicher Form enthalten ist.
- ☐ zusammen mit der internationalen Anmeldung in computerlesbarer Form eingereicht worden ist.
- ☐ bei der Behörde nachträglich in schriftlicher Form eingereicht worden ist.
- ☐ bei der Behörde nachträglich in computerlesbarer Form eingereicht worden ist.
- ☐ Die Erklärung, daß das nachträglich eingereichte schriftliche Sequenzprotokoll nicht über den Offenbarungsgehalt der internationalen Anmeldung im Anmeldezeitpunkt hinausgeht, wurde vorgelegt.
- ☐ Die Erklärung, daß die in computerlesbarer Form erfassten Informationen dem schriftlichen Sequenzprotokoll entsprechen, wurde vorgelegt.

4. Aufgrund der Änderungen sind folgende Unterlagen fortgefallen:

- ☐ Beschreibung, Seiten:
- ☐ Ansprüche, Nr.:
- ☐ Zeichnungen, Blatt:

5. ☒ Dieser Bericht ist ohne Berücksichtigung (von einigen) der Änderungen erstellt worden, da diese aus den angegebenen Gründen nach Auffassung der Behörde über den Offenbarungsgehalt in der ursprünglich eingereichten Fassung hinausgehen (Regel 70.2(c)).

   (Auf Ersatzblätter, die solche Änderungen enthalten, ist unter Punkt 1 hinzuweisen;sie sind diesem Bericht beizufügen).
   siehe Beiblatt

6. Etwaige zusätzliche Bemerkungen:

V. Begründete Feststellung nach Artikel 35(2) hinsichtlich der Neuheit, der erfinderischen Tätigkeit und d r gewerblichen Anwendbarkeit; Unterlagen und Erklärungen zur Stützung dieser Feststellung

1. Feststellung

Neuheit (N)	Ja:	Ansprüche	1-6
	Nein:	Ansprüche	
Erfinderische Tätigkeit (ET)	Ja:	Ansprüche	1-6
	Nein:	Ansprüche	
Gewerbliche Anwendbarkeit (GA)	Ja:	Ansprüche	1-6
	Nein:	Ansprüche	

2. Unterlagen und Erklärungen
   siehe Beiblatt

VII. Bestimmte Mängel der internationalen Anmeldung

Es wurde festgestellt, daß die internationale Anmeldung nach Form oder Inhalt folgende Mängel aufweist:
siehe Beiblatt

Punkt I

1 Die mit Schreiben vom 21.06.01 eingereichten Änderungen erfüllen nicht die Erfordernisse des Art.34 (2) PCT. Die Gründe dafür sind die folgenden:

1.1 Der Ausdruck "einer xylosegehärteten Gelatinekapsel" im vorliegenden Anspruch 7 bringt Sachverhalt ein, der im Widerspruch zu Artikel 34 (2) (b) PCT über den Offenbarungsgehalt der internationalen Anmeldung im Anmeldezeitpunkt hinausgeht. Die Beschreibung in ihrer ursprünglichen Fassung offenbart die Verwendung der erfindungsgemäßen Darreichungsform (*und keine Verwendung "einer xylosegehärteten Gelatinekapsel" wie im vorliegenden Anspruch 6 beansprucht*). Was die Beschreibung in ihrer ursprünglichen Fassung offenbart steht auch nicht im Einklang mit der Feststellung des Anmelders, daß "Anspruch 7 betrifft die Verwendung der erfindungsgemäßen oralen Darreichungsform nach Anspruch 1 zur Verhinderung der Peroxydation" (siehe Schreiben vom 21.06.01, Seite 2, Zeilen 8 bis 10).

1.2 Daher wird die Prüfung auf die ursprünglich eingereichte Fassung der Anmeldung basieren.

Punkt V

2 Es wird auf die folgenden Dokumente verwiesen:

D1: WO-A-93 13761
D2: WO-A-96 36329
D3: DATABASE WPI Section Ch, Week 199711 Derwent Publications Ltd., London, GB; Class B04, AN 1997-112791 XP002143507 -& JP 09 000201 A (AMINO APPU KAGAKU KK), 7. Januar 1997 (1997-01-07)

3 Der Gegenstand des ursprünglich eingereichten unabhängigen Anspruchs 1 ist neu (Art.33 (2) PCT).

3.1 D1 offenbart Weichgelatinekapseln verwendbar als diätetische Lebensmittel, dadurch gekennzeichnet, daß:

i/ das Füllmaterial aus einer Omega-3-Fettsäuren umfassenden Gruppe ausgewählt wird; und
ii/ eine Zusammensetzung, die aus einer Xylose umfassenden Gruppe ausgewählt wird, zur Steuerung der Arzneistofffreisetzung ("controlled release") der Füllmasse zugesetzt wird (siehe Seite 1, Zeilen 9 bis 13, Seite 8, Zeilen 10 bis 19, Seite 11, Zeilen 17 bis 33 und Seite 12, Zeilen 28 bis 32 von D1).
Dieses Dokument offenbart keine mehrfach ungesättigten Fettsäuren, keine xylosegehärtete Gelatinekapsel und keine verzögerte Kapselöffnungszeit.

D2 bringt ans Licht eine orale Darreichungsform:
i/ die eine Omega-3 mehrfach ungesättigte Säure umfaßt;
ii/ deren Umhüllung Poly(ethylacrylate-methylacrylate) ist; und
iii/ die geeignet zur Behandlung der Darmentzündung ist (siehe Seite 1, Zeilen 5 bis 12 und Ansprüche 1 und 7 von D2). Darüber hinaus läßt die Umhüllung sich innerhalb von 60 Minuten und bei einem pH von 5.5 nicht auflösen (siehe Seite 6, Zeilen 24 bis 33 von D2).
D2 offenbart keine xylosegehärtete Gelatinekapsel.

D3 offenbart ein Lebensmittel, das:
i/ geeignet zur Behandlung von Krankheiten der Gedärme ist; und
ii/ eine Omega-3 mehrfach ungesättigte Säure umfaßt.
Dieses Dokument offenbart weder eine xylosegehärtete Gelatinekapsel noch eine verzögerte Kapselöffnungszeit.

3.2 Daher wird der Gegenstand des ursprünglich eingereichten unabhängigen Anspruchs 1 von keinem der D1, D2 oder D3 vorweggenommen.

4 Der Gegenstand des ursprünglich eingereichten Anspruchs 1 beruht auf einer erfinderischen Tätigkeit (Art.33 (4) PCT).

4.1 D1 wird als nächstliegender Stand der Technik angesehen. Daher kann die mit vorliegender Erfindung zu lösende Aufgabe darin gesehen werden, eine orale Darreichungsform zur Verfügung zu stellen, die bei Einnahme:
i/ keine Übelkeit und keinen Magendruck aufweist;
ii/ den unangenehmen Geschmack und das Aufstoßen verhindert;

iii/ das Ranzigwerden deutlich verzögert (siehe Seite 3, Absätze 1 und 2 und Seite 4, Absatz 4 der vorliegenden Beschreibung und Seite 4, Zeilen 30 bis 34, Seite 5, Zeilen 13 bis 14 und Seite 13, Zeilen 9 bis 13 von D1).
Die orale Darreichungsform der vorliegenden Erfindung unterscheidet sich von dieser von D1 dadurch, daß sie mehrfach ungesättigten Fettsäuren und eine xylosegehärtete Gelatinekapsel hat und eine verzögerte Kapselöffnungszeit aufweist. D2 offenbart mehrfach ungesättigten Fettsäuren und eine verzögerte Kapselöffnungszeit aber keines der D2 und D3 offenbart eine xylosegehärtete Gelatinekapsel (siehe 3.1 oben). Darüber hinaus werden die obengenannten technischen Effekte weder in D2 noch in D3 erwähnt (siehe Seite 5, Zeilen 17 bis 20 von D2 und D3).
Deswegen würde der Fachmann ausgehend von der Lehre aus D1, D2 und D3 nicht zur obenerwähnten Aufgabe gelangen.

5 Der Gegenstand der Ansprüche 1 bis 6 ist gewerblich anwendbar im Bereich der Lebensmittelindustrie (Art.33 (4) PCT).

Punkt VII

6 Das Wort "ist" (letzte Zeile des vorliegenden Anspruchs 7) muß vom Wort "sind" ersetzt werden (Regel 91 (1) (b) PCT), da das Wort "die" (zweite Zeile im vorliegenden Anspruch 7) betrifft die "mehrfach ungesättigten Fettsäuren" (siehe auch Seite 2, Absatz 4, Zeilen 1 bis 2 der vorliegenden Beschreibung).

Internationales Aktenzeichen: PCT/EP00/03350
Anmelder: MEDUNA AZRNEIMITTEL GMBH u.a.
Anwaltsalte: K-42 922-25

Ansprüche:

1. Orale Darreichungsform für Nahrungs- sowie Nahrungsergänzungsmittel und Diätetika umfassend mehrfach ungesättigte Fettsäuren in einer xylosegehärteten Gelatinekapsel mit einer verzögerten Kapselöffnungszeit.

2. Darreichungsform nach Anspruch 1, gekennzeichnet, durch Omega-3 mehrfach ungesättigte Fettsäuren mit einem hohen Gehalt an Alpha-Linolensäure.

3. Darreichungsform nach Anspruch 2, dadurch gekennzeichnet, daß sie Perillaöl enthält.

4. Darreichungsform nach einem der Ansprüche 1 bis 3, dadurch gekennzeichnet, daß die Kapselöffnungszeit auf mehr als 45 min. eingestellt ist.

5. Darreichungsform nach einem der Ansprüche 1 bis 4, zur Anwendung bei Fettstoffwechselstörungen und/oder Darmentzündungen, z. B. Morbus Crohn oder Colitis ulcerosa.

6. Darreichungsform nach Anspruch 1, dadurch gekennzeichnet, daß sie Fischöl, Leinöl oder Gamma-Linolensäure enthält.

7. Verwendung einer xylosegehärteten Gelatinekapsel zur Verhinderung der Peroxydation von mehrfach ungesättigten Fettsäuren, die in der als orale Darreichungsform für Nahrungs- sowie Nahrungsergänzungsmittel und für

...12

Diätetika vorgesehenen Gelatinekapsel mit einer verzögerten Kapselöffnungszeit enthalten ist.

8. Verwendung nach Anspruch 76, dadurch gekennzeichnet, daß die Gelatinekapsel Omega-3 mehrfach ungesättigte Fettsäure mit einem hohen Anteil an Alpha-Linolensäure enthält.

9. Verwendung nach Anspruch 8, dadurch gekennzeichnet, daß die Gelatinekapsel Perillaöl enthält.

10. Verwendung nach einem der Ansprüche 7 bis 9, dadurch gekennzeichnet, daß die Kapselöffnungszeit auf mehr als 45 min eingestellt ist.

11. Verwendung nach einem der Ansprüche 7 bis 10, dadurch gekennzeichnet, daß die Gelatinekapsel Fischöl, Leinöl und Gamma-Linolensäure enthält.

Translation

09/719258 8

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference K-42922-25	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP00/03350	International filing date (*day/month/year*) 13 April 2000 (13.04.00)	Priority date (*day/month/year*) 30 June 1999 (30.06.99)
International Patent Classification (IPC) or national classification and IPC A23L 1/30, A61K 9/48, 31/202, 31/232, A61P 1/00		
Applicant MEDUNA ARZNEIMITTEL GMBH		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☒ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
25 August 2000 (25.08.00)	20 August 2001 (20.08.2001)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP00/03350

I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1-5, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages 1-11, filed with the letter of 21 June 2001 (21.06.2001)

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

I. Basis of the report

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

Continuation of: Box I.5.

1 The amendments filed with the letter of 21 June 2001 do not meet the requirements of PCT Article 34(2)(b) for the following reasons:

1.1 The phrase "a xylose-hardened gelatine capsule" in the present Claim 7 introduces substantive matter which, contrary to PCT Article 34(2)(b), goes beyond the disclosure in the international application as filed. The original version of the description discloses the use of the claimed form of administration (*and not the use "of a xylose-hardened gelatine capsule" as claimed in the present Claim 6*). In addition, the disclosure of the original description is inconsistent with the applicant's assertion that "Claim 7 relates to the use of the claimed oral form of administration according to Claim 1 for preventing peroxydation" (see the letter of 21 June 2001, page 2, lines 8-10).

1.2 Consequently, the examination is based on the originally filed version of the application.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-6	YES
	Claims		NO
Inventive step (IS)	Claims	1-6	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-6	YES
	Claims		NO

2. Citations and explanations

1 Reference is made to the following documents:

D1: WO-A-93/13761

D2: WO-A-96/36329

D3: DATABASE WPI Section Ch, Week 199711 Derwent Publications Ltd., London, GB; Class BO4, AN 1997-112791 XP002143507 & JP-A-09 000 201 (AMINO APPU KAGAKU KK) 7 January 1997 (1997-01-07).

2 The subject matter of the originally filed independent Claim 1 is novel (PCT Article 33(2)).

2.1 D1 discloses soft gelatine capsules that can be used as dietary foodstuffs, characterised in that:

i/ the filling material is selected from a group comprising omega-3 fatty acids; and

ii/ a composition selected from a group comprising xylose is added to the filling material to control the release of the drug ("controlled release") (see page 1, lines 9-13; page 8, lines 10-19; page 11, lines 17-33 and page 12, lines 28-32 of D1).

Said document does not disclose multiple unsaturated fatty acids, xylose-hardened gelatine capsules or a delayed capsule opening time.

D2 discloses an oral form of administration:
i/ that comprises an omega-3 multiple unsaturated acid;
ii/ the coating of which consists of poly(ethylacrylate-methylacrylate); and
iii/ that is suitable for treating enteritis (see page 1, lines 5-12 and Claims 1 and 7 of D2). Moreover, the coating will not dissolve in less than 60 minutes and at a pH of 5.5 (see page 6, lines 24-33 of D2).

D2 does not disclose xylose-hardened gelatine capsules.

D3 discloses a foodstuff that:
i/ is suitable for treating bowel diseases; and
ii/ comprises an omega-3 multiple unsaturated acid.

Said document discloses neither a xylose-hardened gelatine capsule nor a delayed capsule opening time.

2.2 Consequently, the subject matter of the originally filed independent Claim 1 is not anticipated by D1, D2 or D3.

3 The subject matter of the originally filed Claim 1 involves an inventive step (PCT Article 33(3)).

3.1 D1 is considered the closest prior art. The present invention can therefore be considered to address the

problem of developing an oral form of administration which when taken:

i/ does not cause sickness or heaviness at the pit of the stomach;

ii/ does not have an unpleasant taste and prevents eructation;

iii/considerably delays rancidity (see page 3, first and second paragraphs and page 4, fourth paragraph of the present description and page 4, lines 30-34; page 5, lines 13-14 and page 13, lines 9-13 of D1).

The oral form of administration of the present invention differs from that of D1 in that it has multiple unsaturated fatty acids, a xylose-hardened gelatine capsule and a delayed opening time. D2 discloses multiple unsaturated fatty acids and a delayed capsule opening time, but neither D2 nor D3 discloses a xylose-hardened gelatine capsule (see section 2.1 above). Moreover, the aforementioned technical effects are not mentioned in either D2 or D3 (see page 5, lines 17-20 of D2 and D3).

Consequently, a person skilled in the art proceeding from the teaching of D1, D2 and D3 would not arrive at the aforementioned problem.

4 The subject matter of Claims 1 to 6 is industrially applicable in the foodstuffs industry (PCT Article 33(4)).

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

The word "is" (last line of the present Claim 7) must be replaced by the word "are" (PCT Rule 91.1(b)), since the word "the" (second line of the present Claim 7) relates to the "multiple unsaturated fatty acids" (see also page 2, fourth paragraph, lines 1 and 2 of the present description).